REMARKS

The sole amendment proffered above is to correct an obvious typographical error in claim 12.

A new inventor declaration is submitted herewith.

The rejection of claims 1-30 under 35 U.S.C. § 112, second paragraph, as being indefinite with the reference to what constitutes "co-crystals of florfenicol" is respectfully traversed. As shown by the article submitted with the IDS filed on January 14, 2010, a co-crystal is well known in the pharmaceutical field as a crystal comprising a pharmaceutically active compound and other non-active compounds, which may include solvents, in the crystals. Accordingly, the skilled person to whom the specification is directed would immediately know that "co-crystals of florfenicol" are crystals containing both florfenicol and non-active compounds, including solvents. While the Final Rejection states this rejection is based on a failure of the specification to state what constitutes a co-crystal, it is respectfully point out that that type of disclosure is not required. As pointed out in MPEP 2164.05(a), "The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public." Accord, *Ex parte Lemoine*, 46 USPQ2d 1420, 1424 (Bd. Pat. App. & Int. 1994) ("In determining if claims are indefinite, claim language is analyzed in light of the teachings of the prior art and in light of the particular application disclosure as it would be interpreted by one having ordinary skill in the art."); *In re Myers*, 161 USPQ 668, 672 (C.C.P.A. 1969) ("the claims of a patent are to be construed in the light of the specification and the understanding thereof by those skilled in that art to whom they are addressed."). Since the term is well

understood and definite to those of ordinary skill in the art, it is respectfully submitted that this rejection should be withdrawn.

The rejection of claims 11-30 under 35 U.S.C. § 103 over Nagabhushan in view Kruse is respectfully traversed.

The present invention relates to a pharmaceutical composition which is an aqueous injectable suspension containing micronized florfenicol at a concentration of up to 500 mg/ml in which the composition does not contain organic solvent beyond that which may be in co-crystals. As pointed out in the opening paragraphs of this application, injectable formulations of this drug were known in the art but they contained organic solvents or mixtures of water and organic solvent. The reason organic solvents were used was that florfenicol has a low solubility in water which is enhanced by the presence of the organic solvents. The claimed invention is based, *inter alia*, on the finding that the organic solvent makes the florfenicol susceptible to hydrolyzation because of the increased dissolution but aqueous solutions free of organic solvents do not hydrolyze micronized florfenicol.

The Nagabhushan reference is merely confirmatory of the prior art described in the application. It describes various florfenicol formulations including aqueous formulations as pointed out in the Office Action, but all such aqueous composition also contain organic solvents. For example, formulation 1 noted by the Examiner is an oral suspension which contains 5% by weight of propylene glycol and is not intended for use as an injectable. Formulation 5, also noted by the Examiner, is not a suspension as here claimed, but is a solution in which the drug is dissolved in 500 mg/ml of N,N-dimethylacetamide. There is nothing in this reference which teaches or suggests the

presence of micronised florfenicol or a substantially water-insoluble complex, co-crystal or salt thereof (in any concentration) in an aqueous injectable suspension which is free of organic solvents. All aqueous florfenicol formulations in this reference contain organic solvent.

The Final Rejection asserts that the Nagabhushan teaches at column 7, lines 27-67 that florfenicol can be formulated in inorganic solvents, and apparently on the fact that water is inorganic. The assertion is apparently based on the strange (and likely inadvertent) definition of "inert organic" solvent as including "inorganic" solvents. In any event, it is respectfully pointed out that assertion is not correct. The cited section of Nagabhushan is a description of the preparation of flurfenicol. Here, the "inert organic" solvent (preferably in tetrahydrofuran, dioxane or tetrahydropyran) is used during the fluorination of a precursor compound, which after deprotection of one group is further reacted with another material in the presence of, for instance, a lower alkanol. The end product is then isolated and purified by removing the solvents and treating the residue (col. 8, lines 58-63). Thereafter the product is formulated for various modes of administration but none of the formulations disclosed are both aqueous and lack the presence of an organic solvent. Thus, while this reference may teach aqueous compositions containing flurfenicol, it does not teach or suggest an aqueous suspension of flurfenicol which does not also include an organic solvent.

The Kruse reference has been cited to teach various aspects of the claims but not to teach or suggest an injectable suspension flurfenicol which lacks organic solvent. Accordingly, the basic deficiency in Nagabhushan is not eliminated by modifying that reference by Kruse.

Because of the basic deficiencies in the combination of references discussed above, it is not necessary to address any of the other contentions made in the rejection. Nevertheless, the lack of response should not be taken as acquiescence but is merely an indication that the assertions made are moot.

In light of the foregoing considerations, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited.

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